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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/412,284 10/05/99 ALLAWAY

G 43966-CA-PCT

EXAMINER

HM12/0911

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NEW YORK NY 10036

ART UNIT	PAPER NUMBER
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1648
DATE MAILED:

09/11/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/412,284

Applicant(s)
Allaway, G., et al.

Examiner
Jeffrey S. Parkin, Ph.D.

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/18/01
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 9, 10, and 15-19 is/are pending in the application.
- 4a) Of the above, claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 9, 10, and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Serial No.: 09/412,284
Applicants: Allaway, G., et al.

Docket No.: 43966-CA-PCT
Filing Date: 10/05/99

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of receipt and entry of the Amendment filed 18 June, 2001, wherein claims 7, 9, and 10 were amended and new claims 15-19. Claims 7, 9, 10, and 15-19 are pending in the instant application. Applicants are advised that
5 newly submitted claims 18 and 19 are directed to an invention that is independent or distinct from the invention originally claimed. The claims are directed toward a different methodology (e.g., a method of preparing a composition) while the extant claims are directed toward a specific product (e.g., an antibody) and a method
10 of using said product to inhibit the fusion and entry of HIV-1 macrophage-tropic primary isolates. The newly presented methodology is directed toward a different inventive concept and employs fundamentally different steps as compared to the methodology currently under examination. Since applicant has
15 received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims are withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. §
20 1.142(b) and M.P.E.P. § 821.03).

35 U.S.C. § 112, Second Paragraph

2. The previous rejection of claims 9 and 10 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly
25 point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in response to applicants' amendment.

35 U.S.C. § 112, First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

5 The specification shall contain a written description of the
invention, and of the manner and process of making and using it, in
such full, clear, concise, and exact terms as to enable any person
skilled in the art to which it pertains, or with which it is most
nearly connected, to make and use the same and shall set forth the
best mode contemplated by the inventor of carrying out his
10 invention.

4. Claims 7, 9, and 10, as well as newly presented claims 15-17,
are rejected under 35 U.S.C. § 112, first paragraph, because the
specification does not reasonably enable any person skilled in the
15 art to which it pertains, or with which it is most nearly
connected, to make and/or use the invention commensurate in scope
with these claims. Applicants argue that the claims are fully
enabled and provide two exhibits (B and C) in support of this
argument. Applicants' arguments have been carefully considered but
20 are not deemed to be persuasive for the reasons of record
previously set forth in Paper no. 10 and as further addressed
below.

Concerning the reliance upon the exhibits, applicants are
reminded that the effective filing date of the instant application
25 is 07 June, 1996. Both publications presented in the exhibit were
published well after the effective filing date (1999 and 2000).
Applicants are reminded that in order to overcome a *prima facie*
case for lack of enablement, applicants must demonstrate that the
disclosure was enabled as of the filing of the application (see
30 M.P.E.P. § 2164.05(a)). Publications dated after the filing date
providing information publicly first disclosed after the filing
date generally cannot be used to show what was known at the time of
filing. *In re Gunn*, 537 F.wd 1123, 1128, 190 U.S.P.Q. 402, 405-06
(C.C.P.A. 1976). *In re Budnick*, 537 F.2d 535, 538, 190 U.S.P.Q.
35 422, 424 (C.C.P.A. 1976). Nevertheless, even if the teachings of

these two publications were applicable, they fail to provide sufficient support for the breadth of the claimed invention. These teachings disclose the identification of six specific monoclonal antibodies bearing the designations PA8, PA9, PA10, PA11, PA12, and PA14. However, these publications fail to provide any further illumination pertaining to the structural requirements of any of these antibodies. For instance, what are the amino acid sequences of these proteins? What are their binding specificities? These teachings also fail to provide any guidance pertaining to other non-antibody agents.

Applicants assert that they employed the same or a similar assay to that described in the exhibits. Applicants are reminded that the claims are directed toward **any** agent (which need not be an antibody) or antibody that is capable of inhibiting HIV-1 macrophage tropic cell fusion. Unfortunately, the disclosure of a generic method for identifying fusion inhibitors does not provide any illumination on the structure of the composition claimed. Nothing presented by applicants sheds any illumination on the precise structure of the claimed agent or antibody. Furthermore, the response fails to provide any objective evidence that specifically addresses the concerns previously raised. As previously set forth, the disclosure fails to provide adequate guidance pertaining to a number critical factors, including the following:

1) The breadth of the claimed invention is exceedingly large and fails to receive adequate support in the specification. The claims do not provide any structural limitations whatsoever on the inhibitory agent. Thus, any chemical compound, including *inter alia*, organic compounds, peptide mimetics, and antibodies, may be encompassed by the claims. However, the specification fails to guide the skilled artisan toward those compounds that can reasonably be expected to retain the desired inhibitory activity.

2) The disclosure fails to provide sufficient guidance pertaining to the structural characteristics of those compounds that are capable of inhibiting macrophage-tropic isolates in a specific manner. The disclosure is silent pertaining to the identification
5 of a common inhibitory motif in the agent of interest.

3) The disclosure also fails to provide any guidance pertaining to the molecular determinants of those regions of the viral envelope and cell surface receptor that are involved in fusion. This might enable the skilled artisan to rationally direct molecules toward
10 certain active sites in the fusion reaction. However, without sufficient guidance pertaining to a suitable molecular target, the skilled artisan has only been extended an undue invitation to further experimentation to try to ascertain which compounds might function in the desired manner.

4) The prior art is unpredictable and fails to provide sufficient illumination pertaining to the structural constraints governing viral-cell fusion. Most successful antiviral agents have been directed against well-characterized enzymatic sites (Hirsch et al., 1997). For instance, protease inhibitors are directed toward an
15 enzymatically active site that has been identified through x-ray crystallography structures of the enzyme. However, no such guidance is available for the current target of interest.

5) The disclosure fails to provide sufficient working embodiments to enable the breadth of the claimed invention.

6) Legal precedence dictates that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification. *In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (C.C.P.A. 1970). *In re Vaeck*, 20 U.S.P.Q.2d 1438 (C.A.F.C. 1991). *In re Angstadt*, 537 F.2d 498, 502-03, 190 U.S.P.Q. 214, 218
25 (C.C.P.A. 1976). Thus, when all the aforementioned factors are considered in toto, it would clearly require undue experimentation from the skilled artisan to practice the claimed invention.
30

35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The previous rejection of claims 11-14 under 35 U.S.C. § 102(b) as being anticipated by Vanini et al. (1992), is moot in view of the cancellation of these claims.

7. The previous rejection of claims 7-10 under 35 U.S.C. § 102(a) as being anticipated by Verrier et al. (1997), is hereby withdrawn in response to applicants' arguments.

Finality of Office Action

8. Applicant's amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO**

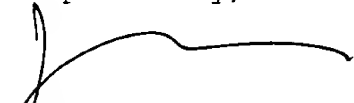
EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

5 9. Correspondence related to this application may be submitted to
Group 1600 by facsimile transmission. The faxing of such papers
must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). Official communications should be
10 directed toward one of the following Group 1600 fax numbers: (703)
308-4242 or (703) 305-3014. Informal communications may be
submitted directly to the Examiner through the following fax
number: (703) 308-4426. Applicants are encouraged to notify the
Examiner prior to the submission of such documents to facilitate
their expeditious processing and entry.

15 10. Any inquiry concerning this communication should be directed
to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-
2227. The examiner can normally be reached Monday through Thursday
from 8:30 AM to 6:00 PM. A message may be left on the examiner's
20 voice mail service. If attempts to reach the examiner are
unsuccessful, the examiner's supervisors, James Housel or Laurie
Scheiner, can be reached at (703) 308-4027 or (703) 308-1122,
respectively. Any inquiry of a general nature or relating to the
status of this application should be directed to the Group 1600
25 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

07 September, 2001


LAURIE SCHEINER
PRIMARY EXAMINER